

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Oral Argument Requested

**DEFENDANTS' REPLY IN FURTHER SUPPORT OF
MOTION TO EXCLUDE OPINIONS OF ZIRUI SONG, M.D., PH.D.**

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INTRODUCTION

Plaintiffs' effort to salvage the unreliable and incomplete opinions of their medical economist, Dr. Zirui Song, collapses because of a basic fact: calculating medical costs for an entire population is more complicated than simply multiplying the average cost of service by the quantity of services provided. Plaintiffs' contrary arguments fail to sustain their burden of proving the admissibility of Dr. Song's overly simplistic opinions for at least two reasons.

First, Dr. Song's assumption that a single meta-analysis can serve as the basis for calculating average medical costs nationwide is not a reliable methodology. Plaintiffs' response sounds in generalities—that experts may rely on meta-analyses, that meta-analyses are sound because they synthesize a large number of other studies, and that Defendants' objections go to issues of weight to be decided by a jury. But these generalities ignore the facts, which show that the 19 studies underlying the one meta-analysis on which Dr. Song relies confirm that average costs vary widely. For that reason, cases excluding experts who rely on the results of a single study without attempting to reconcile it with other conflicting data are squarely on point and support exclusion of Dr. Song's opinions here.

Second, Plaintiffs' arguments also fail to address the gaping holes in Dr. Song's analysis. For example, Dr. Song takes no account of variations on price caused by factors such as geography and insurance policies. The thrust of Plaintiffs'

response is that these variables are not meaningful, but that argument ignores on-point evidence that demonstrates that they are—evidence that Dr. Song should have reconciled with his opinions rather than ignored. Plaintiffs also offer no good defense for Dr. Song’s failure to address the quantity of medical services allegedly required by the class. Instead, they assert that no such work was necessary at this stage. But there is a difference between not *executing* an identified method for calculating quantities and not *identifying* a method at all. Where the method is identified, it may be possible to test its reliability in advance of trial; but that is not possible where, as here, the expert has failed to explain how to account for variations in the relevant patient population. For these reasons, too, his opinions should be excluded.

ARGUMENT

I. DR. SONG’S RELIANCE ON A SINGLE META-ANALYSIS TO SUPPORT HIS OPINION IS GROUNDS FOR EXCLUSION.

Plaintiffs concede, as they must, that Dr. Song’s methodology in forming his class certification opinion consisted of applying a ratio derived by the *Lopez*. study to calculate average healthcare pricing paid by commercial insurers. (See Medical Monitoring Plaintiffs’ Opposition to Defendants’ Joint Motion to Exclude the Opinions of Zirui Song, M.D., Ph.D., [Dkt. 2091](#) (“Pls.’ Br.”), at 3.) While there is nothing inherently wrong with Dr. Song’s consideration of a meta-analysis in forming his opinion, his methodology is singularly based on the *Lopez* study, and he

failed to even consider conflicting evidence, let alone explain why he excluded it. This constitutes an unreliable methodology. *See, e.g., Hoeftling v. U.S. Smokeless Tobacco Co., LLC*, CV 19-3847, 2021 WL 6051382, at *5 (E.D. Pa. Dec. 21, 2021) (excluding expert opinion for ignoring recent studies that reached an opposite conclusion); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 782 (D.S.C. 2016) (failure to address adverse meta-analyses rendered methodology unreliable); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 860 (E.D.N.C. 2015) (failure to employ reliable methodology in selecting underlying studies to form his opinion rendered expert's testimony inadmissible); *see also*, Ann. Manual Complex Lit. § 23.272 (4th ed.) ("Questions regarding the reliability of aggregated evidence can arise . . . where the expert considers several studies, none of which would support the expert's conclusions by itself, but when taken together form the basis for the proffered opinion.").

Notably, Plaintiffs do not cite any cases that support the proposition that a single meta-analysis may form the basis for a reliable expert opinion. Instead, Plaintiffs cite to inapposite cases for the general proposition that specific criticisms of individual studies go to the weight of an expert's testimony, not admissibility. But this is not a case where the parties' experts simply disagree about the quality or applicability of various studies. Here, there is no dispute that Dr. Song only considered a single source of aggregated data, and he did not undertake any analysis

of conflicting studies. This approach lacks scientific rigor and is inherently unreliable.

Plaintiffs also attempt to distinguish a case from this district where the court excluded expert testimony that, like Dr. Song's testimony here, was based entirely on a meta-analysis. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 606 (D.N.J. 2002), *aff'd*, 68 F. App'x. 356 (3d Cir. 2003) (unpublished) (excluding expert witness for reliance on a meta-analysis while failing to discredit studies that reached a different conclusion). Specifically, in *Magistrini* an expert was excluded where he based his opinion on an aggregation of 14 studies, but "did not adequately explain his methods for assessing the internal validity of the studies that he relied upon in rendering his opinion." *Id.* at 605. This is analogous to Dr. Song's methodology here. He relies entirely on the *Lopez* study to support his Medicare-to-commercial insurance pricing ratio, but provides no analysis of the 19 studies that *Lopez* aggregates. And, like the expert in *Magistrini*, Dr. Song provides no discussion of the studies which contradict *Lopez*. This is a fatal methodological error that Plaintiffs cannot explain away by simply arguing that it goes to weight rather than admissibility.

II. PLAINTIFFS DO NOT ADDRESS THE FUNDAMENTAL FLAWS IN DR. SONG'S "COMMON METHODOLOGY."

Plaintiffs' response mirrors Dr. Song's opinion insofar as it makes no attempt to address the staggering breadth of variations in healthcare pricing that are

implicated by the massive scope of Plaintiffs’ proposed medical monitoring classes. Indeed, Plaintiffs’ response brief is silent as to the numerous factors that contribute to variation in commercial healthcare pricing. Likewise, Plaintiffs make no attempt to address variance on the quantity side of Dr. Song’s equation. But these are not merely issues for another day, as Plaintiffs argue. Dr. Song is required to address them now, prior to class certification, in order to demonstrate that his “common methodology” is reliable, relevant, and can ultimately be applied to calculate spending.

A. Plaintiffs Do Not Address Variations in Price.

Plaintiffs completely ignore the factors that cause prices to vary from one market to the next, even though the putative class members hail from across the United States. As Defendants’ medical economist, Dr. Chan, explained,

prices may vary based on numerous other factors, such as the negotiating power between specific insurers and providers, patient’s location, the quality and location of the place of service, and the type of service provider (facility v. nonfacility). Even if Professor Song’s analysis were using accurate average prices for services nationally, they may not be the appropriate average prices that would be incurred by the proposed class members.

(Chan Rep., [Dkt. 2032-5](#), ¶ 117.) Similarly, “variation in patient cost sharing [insurance] arrangements further exacerbates the substantial variation in prices paid

for screening services.” (*Id.* ¶ 126.) And all of these factors will change over time in ways that Dr. Song does not and cannot address.¹ (*Id.* ¶ 127.)

The only source of price variation that Plaintiffs even attempt to address is geography, and Plaintiffs do not offer a substantive discussion. Instead, they criticize Defendants for failing to provide “citation or support following Defendants’ bold assertion that ‘the geographical variation between commercial insurers in one location and those in another is so great that it cannot possibly be accounted for by a single meta-analysis purporting to average prices.’” (Pls.’ Br. at 16.) But it is Plaintiffs’ burden to demonstrate that Dr. Song’s testimony is admissible under Rule 702. And in any event, Dr. Chan *does* provide empirical evidence demonstrating why Dr. Song’s failure to account for geographical pricing variation renders his methodology unreliable:

A 2010 study of metropolitan healthcare markets in eight states found that average inpatient hospital payment rates of four large national commercial insurers ranged from 147 percent of Medicare to 210 percent of Medicare across markets. Some outlier hospitals received even greater markups over Medicare: one hospital was paid almost five

¹ Plaintiffs cite to two inapposite cases where experts were permitted to testify regarding future medical expenses. *See Mihalick v. Delvaux*, Civil Action No. 21-93, 2022 WL 657575 (W.D. Pa. Mar. 4, 2022); *Diaz v. Carnival Corp.*, 544 F. Supp. 3d 1352 (S.D. Fla. 2021) Notably, both cases involved single personal injury plaintiffs with established injuries, not medical monitoring class actions. Moreover, the experts in these cases provided an actual estimate of future medical costs based on an assessment of the individual plaintiffs and their anticipated future care, as opposed to Dr. Song’s incomplete, untested equation related to a population of asymptomatic class members.

times Medicare rates for inpatient services, and another was paid over 7 times Medicare rates for outpatient services."").)

(Chan Rep. ¶ 109.)

In short, Plaintiffs have no answer for Dr. Song's total failure to address pricing variation, other than to point to the *Lopez* study, which does not adequately control for these variables.

B. Plaintiffs Do Not Address Variations in Quantity.

Consistent with Dr. Song's testimony, Plaintiffs concede that Dr. Song did no work—nor was he asked—to address the quantity variable, which is one half of his common spending equation. (Pls.' Br. at 21 ("Dr. Song has solved one half of the equation—i.e. prices—ultimately the other half—i.e. quantities of services for the future class and subclasses—will necessarily be determined at a later date."").) Even assuming, *arguendo*, that this is a valid approach, and accepting Dr. Song's conclusion that it would be *possible*, after a class is defined and certified, to factor in patient variation, Dr. Song still has an obligation to demonstrate how he would account for this variation in his common methodology. Yet, Dr. Song has never explained how his equation would account for the disparate "insurer mix, site of care composition, and network status of the providers for the patient population," although he admits these are relevant considerations. (Song Rep. [Dkt. 2032-3](#), ¶ 39.) Likewise, he does not indicate what assumptions he would apply regarding "life expectancy and the development of medical conditions (e.g., cancer and other acute

and chronic diseases) that may render the monitoring program less appropriate clinically.” (*Id.*) Rather, Dr. Song merely assures us that this could all be factored into his simplistic equation after the classes are defined and certified. As a result, Dr. Song has not demonstrated that his “common methodology” to calculate spending could ever be applied in the real world, and Plaintiffs do nothing to bridge this gap. This invalidates both his methodology and his ultimate conclusion that medical spending can be calculated on a class wide basis.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants’ Motion to Exclude Dr. Song’s class certification opinions.

Dated: June 16, 2022

Respectfully Submitted:

By: /s/ Clem. C. Trischler

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CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2022, a copy of the foregoing document was served on all counsel of record via CM/ECF.

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